UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA [UNDER SEAL],) CIVIL ACTION NO.
PLAINTIFFS,))
v. [UNDER SEAL],) FILED UNDER SEAL) PURSUANT TO) 31 U.S.C. § 3730(b)(2)
DEFENDANTS.) Jury Trial Demanded)
)

COMPLAINT

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Attorneys for [under seal]

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK

United States of America)
Ex Rel. Charles Bates and Craig Patrick) CIVIL ACTION NO.
)
Plaintiffs,)
)
ν.)
) FILED UNDER SEAL
Unity Hospital (330226); Strong Memorial -) PURSUANT TO
University of Rochester (330285); Mount St.) 31 U.S.C. § 3730(b)(2)
Mary's H.C. (330188); Alamance Regional)
Medical Center (340070); Allegheny General)
Hospital (390050); Altru Health System) Jury Trial Demanded
(350019); Andalusia Regional Hospital)
(010036); Arlington Memorial Hospital)
(450064); Aurora St. Luke's Medical Center)
(520138); Aventura Hospital & Medical)
Center (100131); Avera-McKennan)
University H.C. (430016); Ball Memorial)
Hospital (150089); Banner Thunderbird)
Medical Center (030089); Baptist Health)
Medical Center-Little R (040114); Baptist)
Hospital (100093); Baptist Medical Center-)
East (010149); Baptist Medical Center-)
South (010023);Baptist Memorial Hospital-)
Collierville (440217); Baptist Memorial l-)
Golden Triangle (250100); Baptist Memorial)
Hospital-Memphis (440048); Baptist-St.)
Anthony's Health System-Ba (450231);)
Baxter Regional Medical Center (040027);)
Bay Health Medical Center-Kent General)
(080004); Bay Medical Center (100026);)
Bethesda Memorial Hospital (100002);)
Biloxi Regional Medical Center (250007);)
Bloomington Hospital (150051); Bon)
Secours St. Francis Health System (420023);)
Bon Secours St. Mary's Hospital (490059);)
Botsford Hospital (230151); Cape Cod)
Hospital (220012); Cape Coral Hospital)
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(100244); Capital Regional Medical Center
(100254); Caritas Holy Family M.C.
(220080); Cedars-Sinai Medical Center
(050625); Charleston Area Medical Center-
General (510022); Chesapeake General
Hospital (490120); Christ Hospital (360163);)
Citrus Memorial Hospital (100023);
Cleveland Clinic Hospital (360180);
Coliseum Northside Hospital (110201);
Community Hospital Anderson (150113);
Community Hospital (060054); Community
Medical Center (270023); Community
Medical Center (310041); Conemaugh
Memorial Medical Center (390110); Conroe)
Regional Medical Center (450222); Conway)
Medical Center (420049); Conway Regional)
Medical Center (040029); Crestwood
Medical Center (010131); Cullman Regional)
Medical Center (010035); Davis Hospital & )
Medical Center (460041); Davis Regional
Medical Center (340144); Deaconess
Hospital (150082); Decatur General Hospital)
(010085); Delaware County Memorial
Hospital (390081); Denton Regional Medical)
Center (450634); Des Peres Hospital
(260176); Dixie Reg. Medical Center-River
Road Ca (460021); Doctors Hospital of
Sarasota (100166); Duncan Regional
Hospital (370023); Durham Regional
Hospital (340155); East Cooper Regional
Medical Center (420089); Edmond Medical
Center (370148); Eisenhower Medical
Center (050573); El Dorado Hospital
(030080); Eliza Coffee Memorial Hospital
(010006); Elliot Hospital (300012); Erlanger)
Medical Center (440104); Faith Regional
Health Services (280125); Fawcett Memorial)
Hospital (100236); Flagstaff Medical Center)
(030023); Florida Hospital Orlando
(100007); Florida Hospital-Fish Memorial
(100072); Florida l-Heartland M.C.
(100109); Forrest General Hospital
(250078); Fort Walton Beach Medical
Center (100223); Garden City Osteopathic
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Hospital (230244); Garden Park Medical)
Center (250123); Genesis Medical Center-)
Davenport (160033); Genesis-Bethesda Care	;)
System (360039); Genesys Reg.M.C.Health)
Park (230197); Glendale Adventist Medical)
Center (050239); Good Samaritan Regional)
Health Care (140046); Good Shepherd)
Medical Center (450037); Greenville)
Memorial Hospital (420078); Gwinnett)
Medical Center (110087); Halifax Medical)
Center (100017); Hanover Hospital)
(390233); Harrison Memorial Hospital)
(500039); Haywood Regional Medical)
Center (340025); Heartland Spine &)
Specialty Hospital (170195); Hendrick)
Medical Center (450229); Hoag Memorial)
Hospital Presbyterian (050224); Hospital for)
Special Surgery (330270); Huntsville)
Hospital (010039); Hutcheson Medical)
Center (110004); Iberia Medical Center)
(190054); Indiana Orthopaedic Hospital)
(150160); Innovis Health-Dakota Clinic)
(350070); INTEGRIS Baptist M.C.of)
Oklahoma (370028); Jackson Hospital &)
Clinic (010024); Jackson Purchase Medical)
Center (180116); Jefferson Regional Medical	l)
Center (040071); John D. Archbold)
Memorial Hospital (110038); Johnston)
Memorial Hospital (490053); Kansas Spine)
Hospital LLC (170196); Kaweah Delta)
Hospital (050057); Lake Cumberland)
Regional Hospital (180132); Lakeland)
Regional Medical Center (100157);)
Lakewood Hospital (360212); Laredo)
Medical Center (450029); LDS Hospital)
(460010); Lee Memorial Health System)
(100012); Licking Memorial Hospital)
(360218); Long Beach Memorial Medical)
Center (050485); Louisiana Heart Hospital)
(190250); Lovelace Women's Hospital)
(320017); Lowell General Hospital)
(220063); Martin Memorial Health Systems)
Inc (100044); Mary Black Memorial)
Hospital (420083); Mary Immaculate)
Hospital (490041); Massachusetts General)

Hospital (220071); Medical Center East
(010011); Medical Center of Central
Georgia (110107); Medical Center of South)
Arkansas (040088); Memorial Health
University M.C. (110036); Memorial
Hermann Southwest Hospital (450184);)
Memorial Hermann-Texas Medical Center)
(450068); Mercy General Health Partners)
(230004); Mercy General Hospital (050017);)
Mercy Hospital Fairfield (360056); Mercy
Medical Center of Dubuque (160069);)
Mercy Medical Center of Sioux City)
(160153); Mercy Medical Center (160079);)
Mercy Medical Center (160083); Mercy
Medical Center (380027); Mercy Medical)
Center (520048); Methodist Hospital
System, The (450358); Methodist Medical)
Center of Oak Ridge (440034); Methodist)
University Hospital (440049); Middletown)
Regional Hospital (360076); Mission)
Hospitals-Memorial Campus (340002);)
Mizell Memorial Hospital (010007); Mobile)
Infirmary Medical Center (010113); Mount)
Sinai Medical Center (100034); New Albany)
Surgical Hospital (360266); New Hanover)
Regional Medical Center (340141); North)
Carolina Specialty Hospital (340049); North)
Florida Regional Medical Center (100204);)
North Fulton Regional Hospital (110198);)
North Mississippi Medical Center-Tupel)
(250004); North Okaloosa Medical Center)
(100122); North Shore University Hospital)
(330106); Northeast Georgia Medical Center)
(110029); Northeast Medical Center
(340001); Northern Nevada Medical Center)
(290032); Northshore Union Hospital
(220035); Northside Hospital-Forsyth
(110005); Northside Hospital-Cherokee
(110008); Northwest Hospital & Medical)
Center (500001); Northwest Medical
Center-Springdale (040022); Norwalk
Hospital (070034); OU Medical Center)
(370093); P&S Surgical Hospital (190246);)
Palmetto Health Baptist-Columbia (420086);)
Palomar Medical Center)

(050115); Parkway Medical Center)
(010054); Parkwest Medical Center)
(440173); Phoebe Putney Memorial Hospital)
(110007); Physicians Regional Medical)
Center (100286); Pinnacle Health System)
(390067); Pitt County Memorial Hospital)
(340040); Plainview Hospital (330331);)
Presbyterian Orthopaedic Hospital (340153);)
Princeton Community Hospital (510046);)
Provena St. Mary's Hospital (140155);)
Providence Hospital (010090); Providence)
Hospital (230019); Providence Memorial)
Hospital (450002); Providence St. Peter)
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(100000) D II II (010111) DII)
Hospital (250081); Riverside Medical Center)
(140186); Rush Foundation Hospital)
(250069); Rush University Medical Center)
(140119); Rutherford Hospital Inc)
(340013); Sacred Heart Medical Center)
(380033); Sacred Heart Medical Center)
(500054); Saints Medical Center (220082);)
Salem Community Hospital (360185);)
Sarasota Memorial Hospital (100087);)
Satilla Regional Medical Center (110003);)
)
Virginia Beach General (490057); Sentara)
Williamsburg Reg.M.C. (490066); Seton)
Medical Center/450056 (450056); Sierra)
Medical Center (450668); Singing River)
Hospital (250040); Siouxland Surgery)
(430089); Skaggs Community Health Center)
(260094); Skyline Madison Campus)
)
(110165); Southwest Florida Reg.M.C.)
(100220); Southwestern Medical Center)
(370097); Spartanburg Regional Medical)
Center (420007); Spectrum Health-)
Butterworth Campus (230038); St. Anne's)
* , , , , , , , , , , , , , , , , , , ,)
Center (040020); St. Cloud Hospital)
(240036); St. Francis Care (070002); St.)
Francis Hospital (330067); St. Francis)
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Hospital (440183); St. Francis Hospitals &
Health Centers (150033); St. Francis
Medical Center (260183); St. John Macomb)
Hospital (230195); St. John's Health System)
(150088); St. John's Hospital (260065); St.
John's Mercy Medical Center (260020); St.
John's Pleasant Valley Hospital (050616); St.)
Joseph Hospital (110039); St. Joseph
Hospital (150047); St. Joseph Mercy
Oakland (230029); St. Joseph's Hospital of
Atlanta (110082); St. Joseph's Hospital
(240063); St. Lucie Medical Center
(100260); St. Luke's Hospital of Kansas City)
(260138); St. Luke's Hospital (100151); St. )
Luke's Hospital (510067); St. Marys
Hospital Medical Center (520083); St.
Mary's Hospital (520019); St. Mary's
Medical Center of Saginaw (230077); St.
Mary's Medical Center (240002); St. Vincent)
Health System (040007); St. Vincent Health-)
St. Joseph Hospital (150010); St. Vincent's
Hospital (010056); Strong Memorial I-
University of Roches (330285); Summit
Medical Center (440150); Sumner Regional )
Medical Center (440003); Sunrise Hospital
& Medical Center (290003); Tacoma
General Hospital (500129); Tampa General
Hospital (100128); Tanner Medical Center
(110011); Terrebonne General Medical
Center (190008); Texas Spine & Joint
Hospital, The (450864); Trinity Medical
Center (010104); Tucson Medical Center
(030006); UHS ls-Binghamton General
(330394); United Regional Healthcare
System (450010); Via Christi Reg. Medical
Center-St. Fra (170122); Walker Baptist
Medical Center (010089); Warren Hospital
(310060); Watsonville Community Hospital )
(050194); Wayne Memorial Hospital
(340010); Wellmont Holston Valley Medical)
Center (440017); Wenatchee Valley Hospital)
(500148); Western Plains Medical Complex
(170175); White Plains Hospital Center
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(330304); Williamsport Hospital & Medical)
Center (390045); Winchester Medical)
Center (490005); Winter Haven Hospital)
(100052); Woodland Medical Center)
(010143); Yavapai Reg. Medical Center-)
West (030012); York Hospital (390046))
-)
Defendants)

COMPLAINT

Plaintiffs and <u>qui tam</u> relators Charles Bates and Craig Patrick, through their attorneys Phillips & Cohen LLP and Chamberlain & D'Amanda, for their Complaint against defendant hospitals, allege as follows:

I. INTRODUCTION

- 1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent statements, records, and claims made and caused to be made by the defendants and/or their agents and employees in violation of the Federal False Claims Act, 31 U.S.C. §3729 et seq., ("the FCA" or "the Act").
- 2. This <u>qui tam</u> case is brought against the defendant hospitals for submitting false and/or fraudulent claims for inpatient kyphoplasty services to the Medicare program, even though medical necessity required only an outpatient site of service. As a direct result of the defendants' improper practices, the federal treasury has been damaged in substantial amount.
- 3. Kyphoplasty is a procedure for repairing spinal fractures using an orthopedic bone tamp and bone cement. Kyphon, Inc. (now a subsidiary of Medtronic, Inc.) and its employees and

affiliates pioneered the kyphoplasty procedure, and Kyphon manufactures and distributes the equipment used in the procedure.

- 4. From the beginning, the largest obstacle Kyphon has faced to sales of its product was the extraordinarily high price it charged for its products relative to the reimbursement available to hospitals for outpatient kyphoplasty procedures. Rather than lowering its charges (and thus reducing its 90% profit margin), Kyphon initiated a coordinated nationwide sales campaign to encourage hospitals to allow eligible physicians to perform kyphoplasty by emphasizing the opportunity for hospitals to make a substantial profit by fraudulently classifying all kyphoplasty patients as inpatients.
- 5. The defendants knowingly defrauded the Medicare program by fraudulently classifying kyphoplasty cases as inpatient, when only an outpatient procedure was medically necessary. The defendant hospitals then fraudulently submitted claims to the Medicare program requesting inpatient level reimbursement. Had these cases been properly classified as outpatient services, Medicare would have paid substantially less for these services.
- 6. The system of fraudulent billing, coding and medical documentation practices used by the hospitals to carry out the fraud was initially proposed by Kyphon, and later refined and further disseminated by the defendant hospitals, Kyphon and a network of Kyphon-trained physicians.
- 7. The FCA was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub.L. 99-562, 100 Stat. 3153. Congress enacted the 1986 amendments to enhance and modernize the Government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The

amendments were intended to create incentives for individuals with knowledge of Government frauds to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf.

- 8. The Act provides that any person who: (i) knowingly presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government; (ii) knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims; or (iii) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government; is liable for a civil penalty ranging from \$5,500 up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the federal Government.
- 9. The Act allows any person having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time).
- 10. Based on these provisions, <u>qui tam</u> plaintiffs and relators Charles Bates and Craig Patrick, seek through this action to recover damages and civil penalties arising from the defendants' knowing fraud on the U.S. Government.

II. PARTIES

11. Plaintiff/relator Charles Bates, is a resident of Nashville, Tennessee. Mr. Bates is a former employee of Kyphon, Inc. Mr Bates began his employment as a Spine Consultant for Kyphon in August 2001. Mr. Bates was one of the first local sales representative for Kyphon

before its initial public offering. His responsibilities included developing markets in Alabama and the Florida Panhandle region. As a Spine Consultant, Mr. Bates was responsible for developing relationships with key surgeons in his region, managing surgeon education and training, and coordinating reimbursement initiatives with physicians and hospitals. Mr. Bates was also responsible for establishing new accounts with hospitals, assisting hospitals and physicians with coding and reimbursement questions, and marketing the local surgeon "champions" to referring physicians and potential patients.

- 12. Business in Mr. Bates's territory grew from \$16,000 per month to over \$200,000 per month in nine months. Mr. Bates became a Regional Sales Manager in July 2002. He managed sales during a period of rapid expansion for Kyphon and worked with other Regional Sales Managers, Area Directors, Vice Presidents of Sales, and Reimbursement staff to implement and develop corporate strategies, maintain aggressive growth, and manage profitability of his region. Mr. Bates was given an award for achieving his sales goals in eight consecutive quarters. Mr. Bates' employment with Kyphon ended in July 2005. Prior to being employed by Kyphon, Mr. Bates worked in sales positions at Guidant, Inc., Baxter Healthcare Corporation, and Merit Medical Systems, Inc.
- 13. Plaintiff/relator Craig Patrick is a resident of Hudson, Wisconsin. Mr. Patrick worked for Kyphon as a Reimbursement Manager until January 2006. Relator Patrick is an expert in the managed care and sales arenas with extensive experience working with Medicare, Medicaid, and large third party payers. Mr. Patrick has been involved with sales and reimbursement within the healthcare industry for over ten years.

- 14. At Kyphon, Relator Patrick's responsibilities included developing and executing strategic plans to improve coverage and reimbursement of kyphoplasty. In addition, he worked directly with medical directors of Medicare carriers and private payers to ensure reimbursement for kyphoplasty. Mr. Patrick also handled large key accounts within the U.S. to gain further acceptance of kyphoplasty from a reimbursement perspective, including hospitals and large health systems. Mr. Patrick supported the field sales group with direct contact with hospitals, physicians, Medicare carriers and private payers to clear reimbursement hurdles.
- 15. Defendants are hospitals who participated in a common scheme and system to defraud the Medicare program by billing for one-day stay kyphoplasties as inpatient admissions rather than as outpatient procedures. The hospitals all used a common system of fraudulent billing, coding and medical documentation to perpetrate the fraud.
- 16. Relators identified the defendant hospitals through their direct and independent knowledge of the hospitals' billing practices for kyphoplasty procedures. That knowledge consists of a combination of: (1) knowledge that the hospital's protocol and/or the standard practices of physicians operating at the hospital provided for routine admission of one-day stay cases; and/or (2) knowledge that in either 2005 or 2006, more than 60% of the inpatient Kyphoplasty cases in one of the common kyphoplasty DRGs (Diagnosis Related Groups) were one-day stay cases.
- 17. The defendant hospitals are headquartered and operate in various cities across the country. A list of each defendant hospital and its location is attached to this complaint as Exhibit A, which is incorporated into this complaint by reference.

18. A subset of the defendant hospitals are headquartered and/or operate in the Western District of New York. These hospitals include, <u>inter alia</u>: Mount St. Mary's Hospital, Strong Memorial Hospital and Unity Hospital. Hereafter, when referenced separately these hospitals will be described as the "WDNY Hospitals."

III. JURISDICTION AND VENUE

- 19. This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. §1331 and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730.
- 20. Pursuant to 31 U.S.C. §3730(e), Relators have direct and independent knowledge of the fraudulent coding, billing and medical documentation practices used by the defendant hospitals to defraud the Medicare program, and the fact that the defendant hospitals have fraudulently billed the Medicare program for one-day stay kyphoplasties. Moreover, Relators voluntarily provided this information to the Government before filing this Complaint.
- 21. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C.§3732(a) because that section authorizes nationwide service of process and because the defendants have at least minimum contacts with the United States. Moreover, the WDNY Hospitals and some of the other defendant hospitals can be found in, reside in or transact or have transacted business in the Western District of New York.
- 22. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §1391(b) because the WDNY Hospitals and some of the other defendant hospitals can be found in, and transact or have transacted business in the Western District of New York, and because acts proscribed by the False Claims Act occurred in the district. Moreover, all of the defendant

hospitals participated in a common scheme to defraud the Medicare program. All of the hospital defendants worked together, either directly or through Kyphon and/or the network of Kyphon-trained physicians, to develop, share and implement the system of fraudulent coding, billing and medical documentation used to defraud the United States. The result of this common fraudulent scheme was the submission of a series of fraudulent claims, the validity of which depended upon questions of law or fact common to all of them.

IV. <u>BACKGROUND</u>

A. THE MEDICARE PROGRAM

1. General Program Features

- 23. Medicare is a federally-funded health insurance program primarily benefitting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. Medicare, the nation's largest health insurance program, provides health insurance to people age 65 and over, those who have end-stage kidney failure, and certain people with disabilities.
- 24. The Medicare program has four parts: Part A, Part B, Part C and Part D.

 Medicare Part A covers the cost of hospital inpatient stays and post-hospital nursing facility care.

 Medicare Part B covers the costs of physician services, certain pharmaceutical products,

 diagnostic tests and other medical services not covered by Part A. Medicare Part C covers certain

 managed care plans, and Medicare Part D provides subsidized prescription drug coverage for

 Medicare beneficiaries.
- 25. The Medicare program is administered through the Department of Health and Human Services ("HHS"), Centers for Medicare and Medicaid Services ("CMS").

- 26. Much of the daily administration and operation of the Medicare program is managed through contracts with private insurance companies that operate as Fiscal Intermediaries. Fiscal Intermediaries are responsible for accepting claims for reimbursements under Medicare Part A (and some claims under Part B), and making payments for such claims. "Medicare Carriers" are responsible for accepting and paying the remainder of claims for reimbursements under Medicare Part B
- 27. In New York, Empire Medicare Services is the Part A Fiscal Intermediary. Blue Cross/ Blue Shield of Western New York is the Part B Medicare Carrier for Western New York.

2. Medicare Payment Procedures for Inpatient and Outpatient Procedures

- 28. Under Medicare rules, different settings of care have different payment systems. In the hospital inpatient setting, the payment amount is determined by the Diagnosis Related Group ("DRG") that describes the case. DRGs are groups of clinically similar diagnoses and/or procedure codes, which are presumed to have similar resource utilization. Medicare pays a fixed amount per case for each DRG. Except in exceptional circumstances, a DRG's pre-determined reimbursement rate is paid to the hospital regardless of how long the patient stays in the hospital or the number of services provided.
- 29. Payments for outpatient hospital services are also based on bundled, per-case payment system. Hospitals use Ambulatory Payment Classification ("APC") codes to bill for costs associated with outpatient services. Similar to the DRG-based payment system for inpatient services, Medicare reimburses hospitals for outpatient services through standardized payments determined by the APC to which the claim is assigned.

- 30. Each claim is assigned one or more APCs based on the procedure codes (<u>i.e.</u>, HCPCS code, as described below) included on the claim form. Unlike inpatient DRG payments, where the hospital generally receives only one DRG payment per case, hospitals can receive multiple APC payments for the same outpatient case, depending on the nature of the services provided.
- 31. Furthermore, in cases where the DRG or APC payment(s) for a given inpatient or outpatient case were substantially less than the hospital's costs to provide those services, Medicare rules provided that the hospital would receive additional "outlier" payments for that case. For example, after April 1, 2002, a hospital would receive an outlier payment for an outpatient case if the hospital's costs were greater than 3.5 times the APC payment. The outlier payment would be 50% of the difference between the hospital's cost and 3.5 times the APC payment.
- 32. Physician services provided to either inpatients or outpatients are billed and reimbursed separately from the hospital's DRG or APC-based payment. Physician services are reimbursed through a payment system called Resource Based Relative Value Scale ("RBRVS"). In the RBRVS system, payments for services are determined by the resource costs needed to provide them. Payments are calculated by multiplying a standardized measure of the amount of resources the procedure is expected to require (Resource Based Relative Value Units or RBRVUs) by a region-specific payment rate (conversion factor).
- 33. RBRVS payments are based on the Healthcare Common Procedure Coding System ("HCPCS"). HCPCS is a standardized coding system designed to ensure that Medicare, Medicaid and other federal health care programs pay for services rendered to patients by

attending physicians and other healthcare professionals in accordance with payment schedules tied to the level of professional effort required to render specific categories of medical care. To ensure normalization of descriptions of medical care rendered and consistent compensation for similar work, those Federal programs tie levels of reimbursement to standardized codes.

- 34. The Current Procedural Terminology ("CPT") codes are a subset of the HCPCS codes (called Level I codes) and are published and updated annually by the American Medical Association ("AMA"). Base CPT codes are five-digit numbers organized in numeric sequences that identify both the general area of medicine to which a procedure relates (such as "Evaluation and Management," "Anesthesiology," "Surgery," "Radiology," or general "Medicine") and the specific medical procedures commonly practiced by physicians and other health care professionals working in that field.
- 35. The instructions that accompany the CPT manual direct providers "not [to] select a CPT code that merely approximates the service provided." Rather, if no accurate service procedure or service exists among the standard CPT codes, providers are instructed to "report the service using the appropriate unlisted procedure or service code" (i.e., the special CPT codes provided for use when none of the standard CPT codes reasonably and adequately describes the specific procedure or service provided).
- 36. Codes listed after each subsection in the CPT Manual and ending in -99 are "unlisted" codes. Correct code assignment occurs after the documentation for the claim is reviewed by the carrier
- 37. Physicians typically submit claims for professional services on Form CMS-1500.

 The claim form sets forth the diagnostic code describing the patient's presenting condition and the

procedural codes. On the claim form, the physician certifies that the services were "medically indicated and necessary to the health of the patient"

3. <u>Medicare Providers' Duty To Submit True Claims, and To Correct Any Known Prior False Claims Statements</u>

- 38. Federal law specifically prohibits providers from making "any false statement or representation of a material fact in any application for any . . . payment under a Federal health care program." See 42 U.S.C. § 1320-a-7b(a)(1).
- 39. Similarly, Federal law requires providers who discover material omissions or errors in claims submitted to Medicare, Medicaid, or other Federal health care programs to disclose those omissions or errors to the Government. <u>See</u> 42 U.S.C. § 1320-a-7b(a)(3).
- 40. The requirement that providers be truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program, the Medicaid program, and other Federal and State-funded health care programs. See, e.g., 42 CFR §§ 1003.105, 1003.102(a)(1)-(2).

B. TREATMENT OF VERTEBRAL COMPRESSION FRACTURES

- 41. Osteoporosis is a disease in which bones become fragile and are more likely to break. National Osteoporosis Foundation (www.nof.org). If not prevented or if left untreated, osteoporosis can progress painlessly until a bone breaks. Fractures occur typically in the hip, spine, and wrist.
- 42. When a bone in the spine collapses, it is called a vertebral compression fracture (VCF). These fractures happen most commonly in the thoracic spine (the middle portion of the spine), particularly in the lower vertebrae.

- 43. Spinal or vertebral body compression fractures (VCFs) can have serious consequences, including loss of height, severe back pain, and deformity.
- 44. According to the Food and Drug Administration, osteoporosis causes more than 700,000 spinal fractures each year in the United States.
- 45. If left untreated, a spinal fracture can lead to subsequent fractures, often resulting in a condition called kyphosis. Kyphosis is signified by the "dowager's hump," or rounded back. Kyphosis can compress the chest and abdominal cavity with many potential health consequences. (www.kyphon.com)
- 46. Osteoporosis affects post-menopausal women most severely More than one-fourth of women over age 65 will develop a vertebral fracture due to osteoporosis. Decreased mobility from compression fractures accelerates bone loss. High doses of pain medication, especially narcotic drugs, further limit functional ability.
- 47. Traditional treatment for fractures of the spine was immobilization (bed rest) with bracing and drugs for the pain.
- 48. In 1984, a surgical technique to reduce the pain and loss of function associated with vertebral fractures called "percutaneous vertebroplasty" was developed in France.
- 49. In both vertebroplasty and the later-developed kyphoplasty, bone cement, usually polymethyl methacrylate, is injected percutaneously into the partially collapsed vertebral body under fluoroscopic guidance (fluoroscopy or CT). In vertebroplasty, the bone cement is injected in a semi fluid state.
- 50. Both vertebroplasty and kyphoplasty are minimally invasive procedures performed to treat persistent pain or instability resulting from vertebral compression fractures attributable to

osteoporosis or neoplasms in the bone. The procedures may also be used to treat aggressive hemangiomas.

- 51. Kyphoplasty is a modest innovation on the vertebroplasty procedure. In kyphoplasty, an inflatable bone tamp is introduced into the vertebra and inflated partially to restore vertical height before the cement is injected into the space. Once the vertebra is in the correct position, the balloon is deflated and removed. This process creates a void (cavity) within the vertebral body. In kyphoplasty, the cement may be injected under lower pressure and in a more viscous state than in vertebroplasty.
- 52. In kyphoplasty, the cavity is filled with a bone cement to support the surrounding bone and to prevent further collapse. The cement forms an internal cast that holds the vertebra in place. Generally, the procedure is done on both sides of the vertebral body.
- 53. Both the vertebroplasty and kyphoplasty procedures are of relatively short duration. Medical-grade cement hardens quickly, in 10 to 20 minutes. A CT scan may be performed at the end of the procedure to check the distribution of the cement. The longest part of either procedure is the time involved in setting up the equipment and making sure the needle is positioned in the collapsed vertebra.
- 54. Both vertebroplasty and kyphoplasty may be safely performed as outpatient procedures. Inpatient stays at a hospital would only be expected for the rare cases where the patient is unusually frail or their other medical issues require further monitoring following the procedure. As a result, the vast majority of patients receiving vertebroplasty do so on an outpatient basis.

- 55. In fact, some recent published and peer reviewed articles have documented a lower complication rate with kyphoplasty than vertebroplasty and suggest that kyphoplasty may be a safer and more efficacious procedure than vertebroplasty. According to Kyphon, there may be lower complication rates because of the ability to compact cancellous bone and to create a cavity reduces the potential for extravertebral cement leakage during balloon kyphoplasty. In addition, complications may be lower because of how viscous bone cement is delivered into a cavity under manual control.
- 56. Despite the fact that kyphoplasty has a lower complication rate than traditional vertebroplasty, since 1999, Kyphon has promoted the procedure, and the defendant hospitals and many Kyphon-trained physicians have treated the procedure as one that should be performed with an inpatient one-night stay to maximize the hospital's reimbursement. Through this strategy of pursuing high rates of reimbursement through inpatient admission, the defendant hospitals have made significant profits due to fraudulently inflated Medicare reimbursement.

C. <u>KYPHON CAN SAFELY BE PERFORMED AS AN OUTPATIENT PROCEDURE IN THE MAJORITY OF ONE DAY STAY CASES</u>

1. <u>Medical Necessity and Site of Service</u>

- 57. Medicare requires as a condition of coverage that services be "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). Medicare will not pay for services that are not "medically necessary."
- 58. Providers who wish to participate in the Medicare program must ensure that their services are provided "economically and only when, and to the extent, medically necessary." 42 U.S.C. §1320c-5(a).

- 59. Providers may be excluded from participation in the Medicare program and other Federal or State-funded health care programs, if that provider routinely bills Medicare for medically unnecessary items or services. See 42 CFR § 1003.102.
- 60. The medical necessity requirement applies not only to the performance of specific procedures (such as kyphoplasty) but also to the general level of hospital services provided (e.g., nursing care). The general level of hospital services is generally classified as the "site of service" either inpatient or outpatient.
- 61. Medicare rules provide that, as a general matter, an inpatient site of service is appropriate for a patient who is "admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services." See Medicare Benefit Policy Manual ("MBPM") Ch. 1 § 10. "Generally, a patient is considered an inpatient if formally admitted as an inpatient with the expectation that he or she will remain at least overnight" Id.
- 62. The Medicare rules further provide that when a hospital, through its credentialing committee, makes the decision to allow patients to be admitted to the hospital, the hospital should consider: 1) the severity of the signs and symptoms exhibited by the patient, 2) the medical predictability of something adverse happening to the patient, 3) the need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and 4) the availability of diagnostic procedures at the time when, and at the location where, the patient presents. <u>Id</u>.

- 63. The rules further provide that "[p]hysicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis." Id. (emphasis added).
- 64. This 24-hour benchmark is not a fixed rule, however. Medicare rules specifically provide that the overnight stay and 24 hour benchmarks do not, themselves, justify inpatient status. In other words, the rules require more than that the patient simply spent a certain amount of time in a hospital bed. In order to qualify for an inpatient "site of service" the patient must require an inpatient level of care (e.g., nursing care, access to diagnostic or therapeutic equipment, etc.) for the 24-hour period. <u>Id</u>.
- 65. If a patient requires hospital level services for only several hours, the patient may not be classified as an inpatient. Instead, the patient should be classified as an outpatient in "observation" status until a determination can be made as to whether inpatient admission is necessary. See MBPM Ch. 6 § 20.5(A) (defining observation services).
- 66. This rule applies with particular force to cases where a patient undergoes a scheduled surgical procedure that does not generally require a long inpatient convalescent period. With respect to such situations, the Medicare rules provide:

Minor Surgery or Other Treatment - When patients with known diagnoses enter a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for only a few hours (less than 24), they are considered outpatients for coverage purposes regardless of: the hour they came to the hospital, whether they used a bed, and whether they remained in the hospital past midnight.

MBPM Ch. 1 § 10 (emphasis added).

- 67. In such situations, "coverage of services on an inpatient or outpatient basis is not determined solely on the basis of length of time the patient actually spends in the hospital." <u>Id</u>. In fact, Medicare will pay for a patient to remain in observation status for up to 48 hours. <u>See</u>

 MBPM Ch. 6 § 20.5(A). If the physician would like to observe the patient for several hours after a surgical procedure to ensure that no complications develop, then that justifies observation status and not the inpatient stay advocated by Kyphon.
- 68. The Medicare rules emphasize the strict requirements for inpatient site of service in the regulations used by organizations tasked with reviewing the medical necessity of Medicare claims. The Medicare Quality Improvement Organization ("QIO") Manual provides that a patient may only be classified as an inpatient if the "patient . . . demonstrate[s] signs and/or symptoms severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis." See QIO Manual § 4110.
- 69. The QIO Manual further provides that: "Inpatient care rather than outpatient care is required only if the patient's medical condition, safety, or health would be significantly and directly threatened if care was provided in a less intensive setting."

2. Medical Necessity and Site of Service for Kyphoplasty

70. Applying these rules, most kyphoplasty patients who leave the hospital within a day (hereafter referred to as "one day stay" cases) should be outpatients in observation status. Such one-day stay patients should only be classified as inpatients if the patient presents at the hospital with significant additional clinical issues that warrant hospital inpatient status or the patient requires inpatient-level services after the kyphoplasty has been completed.

- 71. Kyphoplasty is generally performed as a scheduled procedure on patients with a known diagnosis. It is minimally invasive and has a low rate of complications.
- 72. The need for post-operative, inpatient level care is generally minimal because the most common complications occur because of leakage of bone cement. These events are very rare and, significantly, because the cement hardens within minutes any such complications would be readily apparent during or shortly after the procedure.
- 73. In addition, the ameliorative effects of the procedure occur shortly after the procedure is completed. Most patients report that their back pain disappears as soon as the procedure is completed. Patients are also usually able to move and walk around within a few hours of the completion of the procedure.
- 74. Accordingly, under the Medicare rules governing medical necessity and site of service, inpatient classification of kyphoplasty patients is not medically necessary in the vast majority of one-day stay cases. Inpatient classification is only appropriate in those limited number of kyphoplasty cases where the documentation in the patient's medical record demonstrates comorbidities or other factors that justify the provision (or expected provision) of hospital level services for 24 hours or more.

D. <u>MEDICARE REIMBURSEMENT FOR KYPHOPLASTY</u>

75. Kyphoplasty was not assigned its own HCPCS codes until 2005, or its own CPT codes until 2006. Starting in 2005, CMS assigned kyphoplasty to temporary HCPCS procedure codes (C9718 and C9719) designed to allow differentiation and tracking of kyphoplasty, even though the procedure was still primarily billed using CPT code 22899. Starting in January 2006, the AMA assigned kyphoplasty its own specific CPT codes, to replace the use of unlisted

procedure CPT code 22899 (and the temporary HCPCS codes) in most states. The new CPT codes are 22523 (percutaneous vertebral augmentation, including cavity creation, thoracic), 22524 (percutaneous vertebral augmentation, including cavity creation, lumbar), and 22525 (for each additional thoracic or lumbar vertebral body).

- 76. At the time Kyphon began marketing its kyphoplasty kits, vertebroplasty was a well established procedure, with its own CPT code, and an established APC. Because Kyphon chose not to pursue a kyphoplasty-specific HCPCS code until 2004 (effective in 2005) or a CPT code until 2005 (effective in 2006), the reimbursement paid to hospitals for the APC to which kyphoplasty was assigned was the lowest available for that class of procedures (e.g., ranging from a base amount of approximately \$80 to \$305 per procedure). (During this period, physicians were paid approximately \$550 for the procedure with approximately \$270 for each additional vertebra whether the procedure was performed on an inpatient or outpatient basis.)
- 77. However, because of Medicare's policies providing for outlier payments (described above), notwithstanding this relatively low APC payment, hospitals were actually paid on average between \$1,000 and \$2,500 for each kyphoplasty procedure billed before kyphoplasty was assigned its own CPT/HCPCS codes.
- 78. When kyphoplasty is performed as an inpatient procedure, the hospital is paid approximately \$6,000 under DRG 234 and between \$8,000 and \$10,000 for DRG 233. The reimbursement for these DRGs is high because they primarily cover hospital cases which, due to the severity and nature of the patient's medical status and the care required, consumed substantial hospital resources over the course of multiple days.

79. When a bone biopsy is performed during an inpatient kyphoplasty, that procedure was billed under DRG 216. DRG 216 also typically covered cases with a far longer average length of stay than kyphoplasty cases. Accordingly, the payment for a DRG 216 case was very high – between approximately \$8500 and \$10,500 on average, and often much higher.

E. TOTAL MEDICARE PAYMENTS FOR KYPHOPLASTY

- 80. According to Kyphon reimbursement materials, Medicare is the single largest payer for kyphoplasty and pays for 85-90% of procedures performed.
- 81. In 2000, slightly more than 1,500 kyphoplasty procedures were performed in the United States. In 2004 this number increased to over 48,000. It is estimated that 60,000 kyphoplasty procedures were performed in the US in 2005.

V. <u>ALLEGATIONS</u>

- 82. Since 1999, Kyphon has aggressively marketed kyphoplasty as an inpatient procedure to induce hospitals to purchase their products. Starting in 1999, Kyphon devised a strategy to market its products which would allow it to maximize profit for its products and avoid lowering the high prices of its products to meet the relatively low rates of reimbursement available to hospitals for outpatient kyphoplasty procedures. The scheme also ensured that the defendant hospitals profited handsomely for allowing Kyphon-trained physicians to perform the procedure.
- 83. The entire goal of the fraudulent scheme was to encourage, train and otherwise assist hospitals to improperly classify outpatient kyphoplasty procedures as one-day stay inpatient admissions in order to fraudulently maximize the hospitals' reimbursement for the procedures. This scheme benefitted not only the hospitals, but also Kyphon and the Kyphon-trained surgeons who performed the procedures. Kyphon benefitted from this scheme because the high profit rates

for the hospitals led them to increase the number of kyphoplasty procedures, thereby spurring an increase in the sales of expensive Kyphon products. The Kyphon-trained physicians benefitted because kyphoplasty offered them an opportunity to move into a new market – minimally invasive treatment of vertebral fractures.

A. <u>KYPHON COACHED HOSPITALS AND PHYSICIANS TO</u> <u>FRAUDULENTLY CLASSIFY OUTPATIENT KYPHOPLASTY CASES</u> AS ONE-DAY STAY INPATIENT CASES

- 84. Starting in 1999, Kyphon sales and marketing departments trained its sales representatives to market its equipment by promoting the kyphoplasty procedure as an inpatient procedure. Specifically, Kyphon managers, including national sales representatives, trained Relator Chuck Bates and hundreds of other typical sales representatives with Kyphon to sell hospitals on the profit to be derived by allowing physicians to perform kyphoplasty as an inpatient procedure, even when the patient was discharged from the hospital the same day as or the day after the procedure.
- 85. The primary focus of the sales force training was on inducing hospitals to admit kyphoplasty patients as inpatients with a one night stay so as to maximize the hospital's revenue and to persuade more hospitals to purchase Kyphon products than would be purchased if procedures were outpatient.
- 86. As part of its strategy, Kyphon sales representatives met with both physicians and relevant personnel at hospitals where the identified physician had admitting privileges. During that credentialing process, Kyphon explained not only the medical aspects of the procedure, but

also the reimbursement landscape. Kyphon used this process to enlist the hospitals into the fraudulent scheme (<u>i.e.</u>, billing all kyphoplasty cases as inpatient only in order to bolster their own bottom line, regardless of medical necessity).

- 87. Sales representatives, including Chuck Bates, were instructed to identify physicians eligible to perform the kyphoplasty procedure and to arrange for training for those physicians.
- 88. Then the sales representative was trained to meet with the Chief Financial Officer, Materials Manager, Operating Room Director, and/or Orthopaedic or Neurological Coordinators at a hospital where a targeted physician had admitting privileges. During that meeting, the representative provided the hospital personnel with information about physician training and reimbursement for the procedure. As part of the sales presentation to hospitals, the Kyphon representatives would explain that the hospital should bill for the procedure by admitting the patient to the hospital and coding the claim to bill under DRG 233 or 234. DRG 233 would make more money for the hospital than DRG 234.
- 89. In general, patients admitted to the hospital for a stay covered by DRGs 233 and 234 (either for kyphoplasty or any of the other conditions and procedures covered by these DRGs) have an average length of stay of 12-14 and 6-8 days according to data from New York's Fiscal Intermediary. By classifying one-day stay patients as inpatients under DRGs 233 or 234, the defendant hospitals sought to maximize their reimbursement by exploiting the high rate intended to cover much longer and costlier stays.
- 90. As outlined above, as a general rule if a patient can leave the hospital the same day as, or the day after, his or her kyphoplasty procedure, then that case should be classified as an outpatient procedure. A one-day case should only be classified as an inpatient case in those

exceedingly rare situations where it appears that a patient will require a long convalescent period at the time of admission, but then the patient recovers remarkably quickly and is discharged within a day. This rule applies with particular force to hospitals where many kyphoplasties are performed, because such hospitals naturally have a better understanding of the clinical profile of the procedure and the fact that a substantial portion of the patients are able to be discharged within several hours of the procedure.

- 91. As set forth above, one factor common to defendant hospitals is the number of one-day stay cases as a share of all inpatient cases. Applying the rules outlined above, that ratio should be very low in fact, there should only be a de minimis number of one-day stay inpatient kyphoplasty cases. Where a substantial number of kyphoplasty cases, and a high share of those cases are one-day stay inpatient cases, those facts indicate a billing pattern that cannot be attributable to mere mistake or happenstance.
- 92. In addition, nearly all of the defendant hospitals billed for twelve or more one-day stay inpatient cases in one of the common kyphoplasty DRGs in 2005 or 2006, and thus should have been aware of the common clinical profile and proper coding treatment for kyphoplasty. These hospitals were then identified as participating in the fraudulent scheme alleged herein if more than 60% of the inpatient cases for any such DRG were one-day cases. Although a ratio of even 10% or 20% one-day stay cases is suspect and could support an allegation of fraud, 60% was used as a cut-off in an abundance of caution.

¹ 2005 and 2006 were the first years when kyphoplasty had a distinct ICD-9 code, and thus kyphoplasty procedures can be reliably distinguished from other procedures based solely on claims data.

- 93. A limited number of the defendant hospitals fall outside of these parameters but have been identified nonetheless because of other information Relators know that supports their inclusion as defendants.
 - B. KYPHON DEVELOPED AN ANALYTIC TOOL SPECIFICALLY TO DEMONSTRATE TO HOSPITALS THE FINANCIAL BENEFITS OF PERFORMING KYPHOPLASTY AS AN INPATIENT PROCEDURE
- 94. When Kyphon first began promoting the kyphoplasty procedure (and selling its Kyphoplasty kits), surgeons and hospitals routinely complained to Kyphon representatives that the hospitals believed that they were losing money on kyphoplasty procedures. To address this concern, beginning in August 2003, Kyphon sales representatives and reimbursement managers began using a custom economic modeling tool, the Hospital Economic Support Model or "HESM." The HESM was used to demonstrate to hospitals the amount of money they could make by allowing physicians to perform kyphoplasty at their facility as long as all kyphoplasty procedures were done on an inpatient basis.
- 95. Regional sales managers and reimbursement managers were given copies of the software to use with their hospitals to show the exact reimbursement that the hospital would receive for each procedure under the DRG.
- 96. The HESM is a spreadsheet with two primary components, a "Reimbursement Overview" and an economic modeling page. The "Reimbursement Overview" provides only inpatient reimbursement information. Specifically, under the heading "Payment Systems" it

outlines only the DRG-based Hospital Inpatient Prospective Payment System. Under the heading "Coding Systems" it again outlines how individual procedure codes lead to specific DRGs.

- 97. Although the model implies that kyphoplasties may be performed on an outpatient basis in some cases by stating that "[a]t this time, the <u>majority</u> of KyphX[®] procedures are performed in the hospital inpatient setting" that suggestion is merely a prelude to the discussion of Medicare reimbursement which focuses entirely on inpatient reimbursement.
- 98. The "Model" sheet of the HESM has three operative sections titled, respectively: (1) "KyphX® Procedure Costs by Level"; (2) "Medicare Reimbursement & DRG Mix"; and (3) "Profit & Loss." There is also a "References" section at the bottom.
- 99. The "KyphX® Procedure Costs by Level" section purports to calculate the cost for a kyphoplasty case, based on the number of "levels" involved (and, correspondingly, number of kyphoplasty kits to be used). The default value for the kyphoplasty kit costs are based on the Kyphon standard prices. The default value for the hospital's other costs are estimated based on the average costs for one-day stay Medicare cases involving ICD-9 Procedure Code 78.49 in 2002, but may be manually overridden. Thus, the HESM assumes that each patient will stay in the hospital one day.
- 100. Next, in the "Medicare Reimbursement & DRG Mix" section the model purports to calculate the "Medicare reimbursement specific to the [hospital.]" This section only includes inpatient reimbursement information. The model assumes that 65% of the kyphoplasties will fall into the higher-paying DRG 233, and 35% into DRG 234, but allows the user to override these percentages. There is no option to reflect the possibility that any outpatient kyphoplasties will be performed on Medicare patients at the hospital.

- 101. Finally, the "Profit & Loss" section purports to calculate the hospital's "mean profit/loss per KyphX® Procedure." (emphasis added). First, this section invites the hospital to enter information about its own experience with kyphoplasty specifically, the number of levels (and, correspondingly, number of kyphoplasty kits) used in kyphoplasties performed at the hospital. Then, the model calculates the mean profit/loss per case by comparing the blended (based on number of levels per case) average cost per case against the blended (based on the ratio of DRG 233 to 234) average reimbursement per case. This calculation continues the prior assumption that the hospital will do no outpatient kyphoplasties.
- 102. As outlined above, Medicare outpatient reimbursement was generally far lower than the cost of the kyphoplasty kit alone. For this reason, an economic modeling tool that failed to include outpatient cost and claims data among the costs considered would be of little value to any hospital that intended to allow kyphoplasties to be performed on an outpatient basis. For such hospitals, it would not matter much how much money they made on inpatient procedures alone the net impact on the hospital would have to balance the profits to be made on inpatient procedures against the loss expected on each outpatient procedure.
- 103. Furthermore, the HESM blends the expected reimbursement inpatient-only reimbursement by DRG to produce an expected average reimbursement level before the average cost per case figures are calculated. The reimbursement for each separate DRG is never compared against the average cost expected for that DRG. Thus, the HESM could not be used to calculate the expected profit per case separately for each DRG. Instead, the only use for the HESM is to calculate the per procedure profit or loss the hospital can expect to see over the course of all kyphoplasties performed at the hospital.

C. KYPHON AND THE DEFENDANT HOSPITALS USED THE PROCESS OF SELECTING PHYSICIANS FOR TRAINING TO FURTHER THE FRAUDULENT SCHEME

- 104. After learning of the substantial difference in the profitability of inpatient and outpatient kyphoplasties, many of the defendant hospitals wanted to ensure that any kyphoplasties would be classified as inpatient procedures.
- 105. For example, Montclair Hospital, which was later bought out by Trinity Medical Center, agreed to allow Dr. Hrynkiw to perform kyphoplasties at the hospital, so long as he treated these cases as inpatient procedures. Montclair had previously blocked all kyphoplasties, but with assurances that Dr. Hrynkiw was going to admit his patients, Montclair was willing to allow kyphoplasties to be performed.
- 106. Kyphon initially focused on recruiting and training orthopedic surgeons and neurosurgeons to perform the kyphoplasty. These doctors generally had admitting privileges at hospitals and admitted patients more regularly than interventional radiologists ("INRs") even though radiologists had performed most vertebroplasty procedures safely for years as outpatient procedures in the radiology lab. Also, surgeons tend to have greater influence than radiologists with hospital credentialing committees and with hospitalization utilization review and quality control managers.
- 107. After having made significant inroads in training surgeons, Kyphon began to train INRs to perform kyphoplasty as well. Kyphon did not initially market to INRs because they do not admit large numbers of patients to the hospital on a regular basis and often perform vertebroplasty as a routine outpatient procedure. Later, though, Kyphon's sales staff pushed to

train INRs because they represented a substantial new pool of physicians who would be doing the procedure and thus driving sales.

- 108. Training INRs was not without risk, however. INRs traditionally performed procedures on an outpatient basis. Accordingly, Kyphon and the defendant hospitals were concerned that the INRs would naturally classify their kyphoplasties as outpatient procedures, thus preventing the hospitals from realizing the benefits of the fraudulent scheme.
- 109. To avoid these problems, Kyphon carefully screened which INRs it trained.

 Before going to training, the physician was required to fill out a questionnaire designed to determine if he or she would question the inpatient-only status of kyphoplasty. In addition, the physician was required to meet the Regional Sales Manager, so that the manager could ensure that the INR was committed to classifying all kyphoplasties as inpatient procedures.
- 110. Kyphon also insisted that the INRs have admitting privileges and a surgeon who would "sponsor" them (<u>i.e.</u>, be available in case of complications). Kyphon made it clear to the INRs that it was unlikely that they would allowed by the defendant hospitals to perform the procedure unless they were all done on an inpatient basis. If the INR questioned the propriety of admitting all kyphoplasty patients, Kyphon would not train them.
- 111. For example, before Kyphon would agree to train Dr. Dorey, an INR who had been performing vertebroplasty on an outpatient basis in the past, the area sales representative, Bart Casey, had to assure Kyphon personnel that Dr. Dorey would admit the kyphoplasty patients. As soon as there was no doubt that Dr. Dorey would admit his patients as inpatients, Dr. Dorey was trained. Dr. Dorey was then permitted to perform kyphoplasties at the Baptist Medical Center East. Since that time, Dr. Dorey has been performing many kyphoplasties.

- 112. Examples of the effect of this policy include the following. Dr. Mark Myers, an interventional radiologist, participated in several training sessions attended by Craig Patrick, where he stated that he performed all of his kyphoplasty cases on an inpatient, one-day stay basis. Chuck Bates also has a powerpoint created by Dr. Meyers stating that kyphoplasty must be classified as inpatient for reimbursement purposes.
 - D. KYPHON COACHED THE STAFF AT THE DEFENDANT HOSPITALS,
 AND THE PHYSICIANS WHO PRACTICED THERE HOW TO
 FRAUDULENTLY CONVERT AN OUTPATIENT CASE TO AN
 INPATIENT ONE-DAY STAY CASE
- 113. Kyphon regularly provided advice to physicians and hospitals on how to avoid audit scrutiny from Medicare and the Medicare Fiscal Intermediaries. The most common way this was done was through the coding and documentation "guidelines" Kyphon representatives gave to physicians and hospitals.
- 114. Kyphon representatives also met with coders and medical record departments to explain to them how to code and bill the hospital charges to ensure payment under DRG 233 or 234, even when the case should have been classified and billed as an outpatient case. Sales representatives were trained to work with hospital coders to ensure they used ICD-9 codes that would track to DRG 233 and DRG 234. Sales representatives were instructed to work with physicians and codes to document as many co-morbidities as possible to fraudulently "justify" DRG 233 when the patient's actual condition did not support that coding.

- 115. The defendant hospitals and Kyphon-trained physicians then used this billing, coding and documentation advice to induce the Medicare program to pay claims that were fraudulently classified as one-day stay inpatient cases.
- 116. For example, after a Kyphon representative trained Cullman Regional Hospital on how to code the kyphoplasty procedure under DRGs 233 and 234, Kyphon employee Trip Treleaven shared an email with Relator Bates from the CFO of Cullman Regional that stated that the hospital was making "a bundle of money" on kyphoplasty and that they should do more.
- 117. Kyphon also corruptly helped hospitals avoid audit scrutiny by improperly promoting the Interqual guidelines. Interqual is a software program purchased by hospitals to assist in compliance with Medicare guidelines. The software reviews the hospital's coding decisions before claims are submitted to Medicare, and flags potential problems. Medicare Fiscal Intermediaries often rely on Interqual's guidelines when performing initial assessments of medical necessity.
- 118. With respect to site of service, although Interqual classifies certain procedures as commonly done on an inpatient basis, this classification does not mean that the procedure may only be done on an inpatient basis, or that it automatically qualifies as medically necessary if done on an inpatient basis. Instead, this classification merely reflects the common practice patterns of physicians practice patterns that, as to kyphoplasty, were influenced by Kyphon's fraudulent scheme. Even when Interqual classifies a procedure as commonly done as an inpatient procedure, the inpatient stay must still be supported by medical necessity.
- 119. In 2003 and early 2004, several hospitals complained to Kyphon that they were having problems justifying kyphoplasty as an inpatient-only procedure because it was not so

classified by Interqual. At that time, Interqual had not specifically reviewed kyphoplasty, but its guidelines classified vertebroplasty as primarily an outpatient procedure.

- 120. Kyphon approached Interqual in February 2004 and asked that it issue guidelines on kyphoplasty. In March 2004, Interqual issued guidelines that indicated that kyphoplasty was generally recognized as an inpatient procedure. Significantly, though, Interqual reached this conclusion largely because its practicing physician consultants reported that kyphoplasty was almost always done as an inpatient procedure. Thus, in other words, because Kyphon, the defendant hospitals, and other providers collaborated to fraudulently treat kyphoplasty as an inpatient-only procedure, Interqual decided that the procedure was generally appropriate for inpatient status.
- 121. Kyphon and the defendant hospitals knew that Interqual's inpatient guideline for kyphoplasty did not, itself, justify inpatient admission. Nonetheless, Kyphon and the hospitals aggressively used the Interqual guideline to further their fraudulent effort to convert procedures that should have been done outpatient into inpatient cases.
- 122. Another way Kyphon "exploited" the guidelines was to notify hospitals that, due to the Interqual guideline, some Medicare plans would not audit the medical necessity of inpatient status for kyphoplasty cases. Thus, as Kyphon suggested, the hospitals could freely classify their kyphoplasty cases as inpatient procedures without fearing a Medicare audit.
 - E. THE DEFENDANT HOSPITALS HELPED DEVELOP, REFINE AND PROPAGATE THE FRAUDULENT BILLING, CODING AND MEDICAL DOCUMENTATION SYSTEM
- 123. Although Kyphon initially developed and disseminated the coding, billing and medical documentation advice used to implement the fraudulent scheme, over time the defendant

hospitals and Kyphon-trained physicians refined and further developed the system. These refinements were then shared with Kyphon, for further dissemination to the other defendant hospitals and surgeons performing the procedure.

- advice to all regional sales managers and Kyphon upper management, outlining how a hospital could recoup the cost of a kyphoplasty procedure in a radiology setting. This email began with a Kyphon spine consultant asking a lab technician at a Minnesota hospital to outline how she coded kyphoplasty cases. The lab technician explained "Kyphoplasty patients are admitted to the hospital post procedure for pain management. Admitting will change the status to IP." and "If the patient goes through as Outpatient, the payment is about \$1,100.00. This does not cover the cost of our supplies." This advice was forwarded to Kyphon's Regional Sales Managers so that they would share the advice with their sales representatives, who, it was expected, would, in turn, share the advice with their hospital clients.
- 125. Hospitals and physicians who were already participating in the fraudulent scheme often served as references for other hospitals or physicians that were considering the viability of the kyphoplasty procedure. Examples of the links and sharing of information between and among the defendant hospitals and the physicians practicing there include the following.
- 126. Dr. Noel, who practiced at Siouxland Surgery Center in North Dakota conducted training programs for physicians who practiced at several area hospitals. During these training sessions, he told those physicians to classify all of their kyphoplasty cases as one-day stay inpatient cases so that the hospital would get paid more. After these training programs, some or

all of the physicians began implementing the fraudulent scheme at surrounding hospitals: Dakota Dunes Hospital in North Dakota and Mercy Hospital in Sioux City, Iowa.

127. Dr. Wilburn Smith practiced at Baptist Medical Center-South in Montgomery, Alabama. Dr. Smith discovered that it was easier to improperly classify outpatient procedures as inpatient procedures if he claimed that he was doing an "open" procedure (i.e., cutting open the patient's back) even though kyphoplasty was not, in fact, an open procedure. Dr. Smith told Relator Bates that he believed all of the surgeons in Alabama should "stick together" and use the same coding practices. Dr. Smith shared his fraudulent coding practices with other surgeons in Alabama, who then used the same techniques. Kyphon representatives routinely gave Dr. Smith's contact information to other surgeons and encouraged them to call him to learn about his fraudulent techniques.

F. THE PARTICIPANTS IN THE FRAUDULENT SCHEME PERFORMED UNNECESSARY BONE BIOPSIES TO FRAUDULENTLY INCREASE REIMBURSEMENT

- 128. Kyphon-trained physicians and the defendant hospitals have also at Kyphon's suggestion performed medically unnecessary bone biopsies as part of kyphoplasty procedures to bolster otherwise weak cases for medical necessity for inpatient site of service, and to increase the level of reimbursement.
- 129. Kyphon sales representatives were instructed by their managers to tell doctors they should purchase and use the device for biopsies to "cover their tracks." Doctors were told that if they performed a biopsy, they did not have to worry about finding a co-morbidity to make sure they were reimbursed under DRG 233, since Medicare paid the hospital more for DRG 216.

- 130. As with all other services, Medicare will only reimburse for a biopsy if it is medically necessary. Notwithstanding this policy, Kyphon sales representatives encouraged and hospitals allowed doctors to biopsy every patient, even if there was nothing to indicate the patient needs a biopsy.
- 131. Hospitals can earn up to \$6000 more per inpatient procedure for a kyphoplasty performed along with a bone biopsy, depending on geography. If the addition of a bone biopsy allowed the hospital to fraudulently claim that a one-day stay case was inpatient rather than outpatient, the hospital stood to gain up to \$9500 in (fraudulent) additional reimbursement.
- 132. In February 2003, Kyphon released their "Bone Biopsy Device," a disposable, stainless steel tube and rod that can be used to take biopsy samples of bone for further evaluation. Kyphon developed this device as part of its scheme to encourage physicians and hospitals that biopsies should be performed in every kyphoplasty.
- 133. Marketing of the bone biopsy procedure was successful. For example, Dr. Sammons performed kyphoplasty procedures at both Crestwood Medical Center and Hunstville Hospital. According to Relator Bates, when the biopsy device was released by Kyphon, the sales force was told to inform physicians that the reimbursement was the highest for the hospital when they did a biopsy. After Sammons was informed of this, he started to perform more biopsies.
- 134. A member of the Carrier Advisory Committee for Noridian told Relator Patrick that many providers recognized that performance of a biopsy every time a kyphoplasty was performed was not medically necessary, but nonetheless it was routinely done simply to secure additional reimbursement for hospitals.
 - G. THE PARTICIPANTS IN THE FRAUDULENT SCHEME SPLIT CASES
 UP IN ORDER TO MAXIMIZE REIMBURSEMENT, EVEN THOUGH

REPAIRING ALL VERTEBRAE AT THE SAME TIME WOULD HAVE BEEN SAFER AND LESS EXPENSIVE

- 135. In general, a separate kyphoplasty kit is required for each vertebrae that is repairedor, in Kyphon's terminology, for each level of the procedure that is performed.
- 136. Because of the high cost of the kyphoplasty kits, many hospitals reported to Kyphon that they were losing money on kyphoplasty procedures that used more than one kit.
- 137. The rule of thumb in the Sales Department was that hospitals would generally make money on 1 level cases, break even on 2 level cases and lose money on 3 levels cases.

 Accordingly, the Sales Representatives did one of two things. They either would give free product to cover the 3 level cases or would encourage physicians to do only 1 or 2 levels at a time on a patient that had multiple fractures in order to make sure the hospital would make money.
- 138. Regarding the first option, Chuck Bates and Jeff Weatherman met with P&S Surgical, which was concerned about reimbursement on multilevel cases. They were performing the cases as one-day inpatient procedures, but reimbursement did not cover 3 level cases. Bates and Weatherman told the hospital that they would give them samples to cover any 3 level cases they performed. P&S Surgical agreed and continued to be a big customer of Kyphon and were happy with the profit they made.
- 139. Under the other option, if a patient required treatment of more than two levels, the doctors were encouraged to have the patient come back for a separate procedure. This would allow the hospital to bill for an entire additional case, and receive an additional full DRG payment.

- 140. In order to encourage physicians to do only 1 or 2 levels at a time, the Sales Representatives were trained to say that doing more than 2 levels at a time was dangerous for the patient (e.g., that the patient could get monomer toxicity from the bone cement). The Sales Representatives were not given, nor do Relators know of, any evidence to support that claim.
- 141. The Medicare program was not the only party harmed by this practice. Medicare beneficiaries are required to pay a substantial copayment each time they are admitted to the hospital. Currently, a Medicare beneficiary has to pay a \$992 copay for days 1-60 of each hospital stay. By sending patients home and bringing them back later, individual Medicare recipients were forced to pay unnecessary additional copayments due to this medically unnecessary unbundling of procedures.
- 142. The patients also suffered the risks associated with anesthesia and surgery multiple times, when they should have been subjected to those risks only once.
- 143. This practice of only doing 1 or 2 levels at a time was designed for the sole purpose of increasing revenue for the hospitals. The defendant hospitals knew that 3 level cases could safely and effectively be performed, as illustrated by their willingness to allow the performance of 3 level cases if they received free product from Kyphon to cover the costs. They knew that by having the patient come back for a separate procedure, they were harming both the Medicare program and the Medicare beneficiaries. However, the defendants saw this as an additional opportunity to maximize their revenue.

H. <u>DEFENDANT HOSPITALS KNOWINGLY PARTICIPATED IN THE</u> <u>FRAUDULENT SCHEME</u>

144. Specific examples demonstrating that the defendant hospitals knowingly participated in the fraudulent scheme include, <u>inter alia</u>, the following.

- 145. While working at the ALTRU Clinic, Dr. Brent Herbel told Craig Patrick "that all his kyphoplasty cases were done in-patient because that was the only way the hospital could make money on the procedure." Over 180 inpatient kyphoplasties were performed at ALTRU in 2005 and 2006.
- 146. Similarly, the administrators at St. Mary's Medical Center also believed that the kyphoplasty procedure was causing the hospital to lose money. The hospital withdrew the complaint after Relator Patrick explained to the administrators that the hospitals were making money by treating the cases as one-day stays.
- 147. Dr. Glesson at Rush University Medical Center in Chicago, Illinois told Relator Patrick that he classified all of his kyphoplasty cases as inpatient cases for reimbursement reasons. Dr. Frank Phillips also practiced at Rush. Dr. Phillips was a Kyphon faculty member and classified all, or nearly all, of his kyphoplasty cases as inpatient procedures.
- 148. Relator Patrick attended several training programs given by Dr. Lieberman, who practices primarily at the Cleveland Clinic Hospital in Cleveland, Ohio. Relator Patrick heard Dr. Lieberman say that he admitted most of his kyphoplasty patients because "you can't make money otherwise."
- 149. Cindy Owens, the Operating Room supervisor at Decatur General Hospital in Alabama complained to Relator Bates that they were losing money on kyphoplasty procedures done by Dr. Robert Ward because Dr. Ward was (properly) classifying his one-day stay cases as outpatient cases. In response to this complaint, Dr. Ward agreed to classify all future one-day cases as inpatient cases. Relator Bates witnessed Ms. Owens then tell a nurse to switch the classification of a case Dr. Ward was then performing from outpatient to inpatient. The nurse

prepared the paperwork to effect the change on the spot, and Dr. Ward stated that he would sign the paperwork changing the case's classification after he finished performing the procedure.

Relator Bates later heard Dr. Ward comment, on several different occasions, that even though he classified all of his kyphoplasty patients as inpatients, he sent most of them home the same day.

- 150. Relator Patrick attended a training session for physicians at Heartland Spine & Specialty Hospital in Overland Park, Kansas. The trainer, who practiced at Heartland, told the other physicians that they should admit all kyphoplasty cases for reimbursement reasons.
- 151. Relator Bates went to John D. Archbold Memorial Hospital in Georgia in March 2003 with Kyphon Spine Consultant Molly Hannan. During that visit he learned that Dr. Khadis was classifying all of his kyphoplasty procedures as inpatients. Ms. Hannan told the physicians in the hospital's emergency room that they should admit all of their kyphoplasty cases as well, and to consult with Dr. Khadis if they had any questions about doing so.
- 152. Dr. Metzger, who practices at Mizell Memorial Hospital in Alabama expressed concern that the hospital would not allow him to do kyphoplasty procedures because the hospital lost money on the procedure. In January 2003, Relator Bates and another Kyphon representative met with Dr. Metzger to explain reimbursement issues and that the hospital would make money as long as he admitted all patients and documented enough comorbidities to ensure that the case was classified as DRG 233. Dr. Metzger later became of the top kyphoplasty surgeons in Mr. Dixon's region.
- 153. Similarly, Kyphon representative Buck Dixon told Relator Bates that Mobile Infirmary Medical Center in Alabama was very cost sensitive, and was limiting the performance of kyphoplasty procedures because of fears about the reimbursement level. Mr. Dixon worked

closely with Dr. Volkman, who practiced at Mobile Infirmary, to ensure that he classified all of his cases as inpatients and regularly performed a bone biopsy to increase reimbursement further.

- 154. In July 2004, while leading a training session on behalf of Kyphon at St. Lukes Hospital in Wisconsin, Dr. Paul Minor stated that hospitals should do the kyphoplasty procedure on an inpatient basis "because you have to play the game with Medicare in order to make money on these things." In 2005 and 2006, over 80% of the kyphoplasty procedures at this hospital were one-day stays.
- 155. That the defendant hospitals knew that kyphoplasty could safely and effectively be performed as an outpatient procedure in the majority of cases is demonstrated by the fact that the hospitals would sometimes switch between performing kyphoplasty as inpatient or outpatient, based on which would pay more. For example, Diego Gimenez, the representative for the Huntsville, Alabama area, told Chuck Bates that "all Medicare was done as inpatient and that Blue Cross / Blue Shield was done as outpatient because Blue Cross / Blue Shield paid more for the procedure as an outpatient."
- 156. Kyphon representative Buck Dixon told Relator Bates that all but one of the surgeons at Providence Hospital in Mobile, Alabama classified all of their kyphoplasty cases as inpatient. The one exception classified all Medicare cases as inpatients, but classified Blue Cross Blue Shield cases as outpatient procedures because the BCBS reimbursement was higher for outpatient cases.
- 157. In such cases, the hospitals were not performing kyphoplasty as an inpatient procedure because they believed it was medically necessary, but rather because it knew that was the way to maximize its reimbursement from the Medicare program.

I. DAMAGES TO THE GOVERNMENT AS A RESULT OF THE FRAUDULENT SCHEME

- 158. In the manner described above, the defendant hospitals submitted thousands of bogus claims to the Medicare program for outpatient kyphoplasty procedures fraudulently classified as inpatient one-day stay cases. The Medicare program then paid the defendant hospitals thousands of dollars more for each of these cases than it would have had the case been properly billed. Every such claim is a false claim within the meaning of the False Claims Act.
- 159. Every claim submitted by the defendant hospitals for kyphoplasty cases involving an unnecessary bone biopsy, or when a case was improperly split into multiple cases, is also a false claim.
- 160. During the course of the fraudulent scheme, defendant hospitals have submitted thousands of false claims to the Medicare program, defrauding the United States of tens of millions of dollars.

COUNT I

False Claims Act 31 U.S.C. §3729(a)(1), (2), (7)

- 161. Plaintiffs reallege and incorporate by reference the allegations in paragraphs 1-160.
- 162. This is a claim for treble damages and penalties under the False Claims Act,31 U.S.C. §3729 et seq.
- 163. Through the acts described above, defendant hospitals knowingly presented, or caused to be presented, false or fraudulent claims, to the United States Government, in order to obtain government reimbursement for health care services provided under Medicare, Medicaid, and other Federal programs.

- 164. Through the acts described above, the defendant hospitals have knowingly made, used and caused to be made and used false records and statements to get false or fraudulent claims paid in order to obtain government reimbursement for health care services provided under Medicare, Medicaid and other Federal programs.
- 165. Through the acts described above, defendant hospitals knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States Government, within the meaning of 31 U.S.C. §3729(a)(7).
- 166. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal conduct.
- 167. By reason of defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

Prayer

WHEREFORE, plaintiffs pray for judgment against the defendant as follows:

- 1. that defendants cease and desist from violating 31 U.S.C. §3729 et seq.;
- 2. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. \$3729;
- 3. that plaintiffs be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

- 4. that plaintiffs be awarded all costs of this action, including attorneys' fees and expenses; and
- 5. that the United States and plaintiffs recover such other and further relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, plaintiffs hereby demand a trial by jury.

Dated: May 29, 2008

PHILLIPS & COHEN LLP Mary Louise Cohen Matthew B. Smith Timothy P. McCormack Phillips & Cohen, LLP 2000 Massachusetts Ave, N.W. Washington, D.C. 20036 Tel: (202) 833-4567

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CHAMBERLAIN & D'AMANDA

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1600 Crossroads Bldg
Two State Street
Rochester, NY 14614
Tel: (585) 232-3730

Fax: (585) 232-3882

ATTORNEYS FOR QUI TAM PLAINTIFF Charles Bates and Craig Patrick

EXHIBIT A TO FEDERAL FALSE CLAIMS ACT COMPLAINT:

LIST OF DEFENDANT HOSPITALS

Provider ID	Hospital Name	Address	City
340070	Alamance Regional Medical Center	1240 Huffman Mill Rd	Burlington
390050	Allegheny General Hospital	320 E North Ave	Pittsburgh
350019	Altru Health System	1200 S Columbia Rd	Grand Forks
010036	Andalusia Regional Hospital	849 S Three Notch St	Andalusia
450064	Arlington Memorial Hospital	800 W Randol Mill Rd	Arlington
520138	Aurora St. Luke's Medical Center	2900 W Oklahoma Ave	Milwaukee
100131	Aventura Hospital & Medical Center	20900 Biscayne Blvd	Aventura
430016	Avera-McKennan University H.C.	800 E 21st St	Sioux Falls
150089	Ball Memorial Hospital	2401 W University Ave	Muncie
030089	Banner Thunderbird Medical Center	5555 W Thunderbird Rd	Glendale
	Baptist Health Medical Center-Little		
040114	Rock	9601 Interstate 630 Exit 7	Little Rock
100093	Baptist Hospital	1000 W Moreno St	Pensacola
010149	Baptist Medical Center-East	400 Taylor Rd	Montgomery
010023	Baptist Medical Center-South	2105 E South Blvd	Montgomery
440217	Baptist Memorial Hospital-Collierville	1500 W Poplar Ave	Collierville
440048	Baptist Memorial Hospital-Memphis	6019 Walnut Grove Rd	Memphis
250100	Baptist Memorial I-Golden Triangle	2520 5th St North	Columbus
450231	Baptist-St. Anthony's Health System	1600 Wallace Blvd	Amarillo
040027	Baxter Regional Medical Center	624 Hospital Dr	Mountain Home
	Bay Health Medical Center-Kent		
080004	General	640 S State St	Dover
100026	Bay Medical Center	615 N Bonita Ave	Panama City
100002	Bethesda Memorial Hospital	2815 S Seacrest Blvd	Boynton Beach
250007	Biloxi Regional Medical Center	150 Reynoir St	Biloxi
150051	Bloomington Hospital	601 W 2nd St	Bloomington
	Bon Secours St. Francis Health		
420023	System	1 St. Francis Dr	Greenville
490059	Bon Secours St. Mary's Hospital	5801 Bremo Rd	Richmond
230151	Botsford Hospital	28050 Grand River Ave	Farmington
220012	Cape Cod Hospital	27 Park St	Hyannis
100244	Cape Coral Hospital	636 Del Prado Blvd	Cape Coral
100254	Capital Regional Medical Center	2626 Capital Medical Blvd	Tallahassee
220080	Caritas Holy Family Medical Center	70 East St	Methuen
050625	Cedars-Sinai Medical Center	8700 Beverly Blvd	Los Angeles
F10000	Charleston Area Medical Center-	FO1 Marris Ct	Charlastar
510022	General Constal Heavital	501 Morris St	Charleston
490120	Chesapeake General Hospital	736 Battlefield Blvd North	Chesapeake
360163	Christ Hospital/360163	2139 Auburn Ave	Cincinnati
100023	Citrus Memorial Hospital	502 W Highland Blvd West	Inverness
360180	Cleveland Clinic Hospital/360180	9500 Euclid Ave	Cleveland
110201	Coliseum Northside Hospital	400 Charter Blvd	Macon

Provider ID	Hospital Name	Address	City
150113	Community Hospital Anderson	1515 N Madison Ave	Anderson
060054	Community Hospital/060054	2021 N 12th St	Grand Junction
270023	Community Medical Center/270023	2827 Fort Missoula Rd	Missoula
310041	Community Medical Center/310041	99 Hwy 37 West	Toms River
390110	Conemaugh Memorial Medical Center	1086 Franklin St	Johnstown
450222	Conroe Regional Medical Center	504 Medical Center Blvd	Conroe
420049	Conway Medical Center	300 Singleton Ridge Rd	Conway
040029	Conway Regional Medical Center	2302 College Ave	Conway
010131	Crestwood Medical Center	1 Hospital Dr	Huntsville
010035	Cullman Regional Medical Center	1912 Alabama Hwy 157	Cullman
460041	Davis Hospital & Medical Center	1600 W Antelope Dr	Layton
340144	Davis Regional Medical Center	218 Old Mocksville Rd	Statesville
150082	Deaconess Hospital/150082	600 Mary St	Evansville
010085	Decatur General Hospital	1201 7th St SE	Decatur
390081	Delaware County Memorial Hospital	501 N Lansdowne Ave	Drexel Hill
450634	Denton Regional Medical Center	3535 S I-35	Denton
260176	Des Peres Hospital	2345 Dougherty Ferry Rd	Saint Louis
460021	Dixie Reg.Medical Center-River Road Ca	1380 E 480 South	St George
100166	Doctors Hospital of Sarasota	5731 Bee Ridge Rd	Sarasota
370023	Duncan Regional Hospital	1407 Whisenant Dr	Duncan
340155	Durham Regional Hospital	3643 N Roxboro Rd	Durham
420089	East Cooper Regional Medical Center	1200 Johnnie Dodds Blvd	Mount Pleasant
370148	Edmond Medical Center	1 S Bryant Ave	Edmond
050573	Eisenhower Medical Center	39000 Bob Hope Dr	Rancho Mirage
030080	El Dorado Hospital	1400 N Wilmot Rd	Tucson
010006	Eliza Coffee Memorial Hospital	205 Marengo St	Florence
300012	Elliot Hospital	1 Elliot Way	Manchester
440104	Erlanger Medical Center	975 E 3rd St	Chattanooga
280125	Faith Regional Health Services	109 North 15th Street	Norfolk
100236	Fawcett Memorial Hospital	21298 Olean Blvd	Port Charlotte
030023	Flagstaff Medical Center	1200 N Beaver St	Flagstaff
100007	Florida Hospital Orlando	601 E Rollins St	Orlando
100072	Florida Hospital-Fish Memorial	1055 Saxon Blvd	Orange City
100109	Florida I-Heartland M.C.	4200 Sun 'n Lakes Blvd	Sebring
250078	Forrest General Hospital	6051 US Hwy 49 South	Hattiesburg
100223	Fort Walton Beach Medical Center	1000 MarWalt Dr	Fort Walton Beach
230244	Garden City Osteopathic Hospital	6245 N Inkster Rd	Garden City
250123	Garden Park Medical Center	15200 Community Rd	Gulfport
160033	Genesis Medical Center-Davenport	1227 E Rusholme St	Davenport
360039	Genesis-Bethesda Care System	2951 Maple Ave	Zanesville
230197	Genesys Reg.M.C.Health Park	1 Genesys Pkwy	Flint
050239	Glendale Adventist Medical Center	1509 Wilson Terr	Glendale
140046	Good Samaritan Regional Health Care	605 N 12th St	Mount Vernon
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Provider ID	Hospital Name	Address	City
	Good Shepherd Medical		
450037	Center/450037	700 E Marshall	Longview
420078	Greenville Memorial Hospital	701 Grove Rd	Greenville
110087	Gwinnett Medical Center	1000 Medical Center Blvd	Lawrenceville
100017	Halifax Medical Center	303 N Clyde Morris Blvd	Daytona Beach
390233	Hanover Hospital	300 Highland Ave	Hanover
500039	Harrison Memorial Hospital/500039	2520 Cherry Ave	Bremerton
340025	Haywood Regional Medical Center	262 Leroy George Dr	Clyde
170195	Heartland Spine & Specialty Hospital	10720 Nall Ave	Overland Park
450229	Hendrick Medical Center	1900 Pine St	Abilene
050224	Hoag Memorial Hospital Presbyterian	One Hoag Dr	Newport Beach
330270	Hospital for Special Surgery	535 E 70th St	New York
010039	Huntsville Hospital	101 Sivley Rd	Huntsville
110004	Hutcheson Medical Center	100 Gross Crescent	Fort Oglethorpe
190054	Iberia Medical Center	2315 E Main St	New Iberia
150160	Indiana Orthopaedic Hospital	8400 Northwest Blvd	Indianapolis
350070	Innovis Health-Dakota Clinic	3000 32nd Ave	Fargo
370028	INTEGRIS Baptist M.C.of Oklahoma	3300 Northwest Expy 100-7010	Oklahoma City
010024	Jackson Hospital & Clinic	1725 Pine St	Montgomery
180116	Jackson Purchase Medical Center	1099 Medical Center Cir	Mayfield
	Jefferson Regional Medical		
040071	Cent/040071	1600 W 40th St	Pine Bluff
110038	John D. Archbold Memorial Hospital	Gordon Ave at Mimosa Dr	Thomasville
490053	Johnston Memorial Hospital/490053	351 Court St NE	Abingdon
170196	Kansas Spine Hospital LLC	3333 N Webb Rd	Wichita
050057	Kaweah Delta Hospital	400 W Mineral King	Visalia
180132	Lake Cumberland Regional Hospital	305 Langdon St	Somerset
100157	Lakeland Regional Medical Center	1324 Lakeland Hill Blvd	Lakeland
360212	Lakewood Hospital	14519 Detroit Ave	Lakewood
450029	Laredo Medical Center	1700 E Saunders	Laredo
460010	LDS Hospital	8th Ave & C St	Salt Lake City
100012	Lee Memorial Health System	2776 Cleveland Ave	Fort Myers
360218	Licking Memorial Hospital	1320 W Main St	Newark
	Long Beach Memorial Medical		
050485	Center	2801 Atlantic Ave	Long Beach
190250	Louisiana Heart Hospital	64030 Hwy 434	Lacombe
320017	Lovelace Women's Hospital	4701 Montgomery Blvd NE	Albuquerque
220063	Lowell General Hospital	295 Varnum Ave	Lowell
100044	Martin Memorial Health Systems Inc.	300 Hospital Dr	Stuart
420083	Mary Black Memorial Hospital	1700 Skylyn Dr	Spartanburg
490041	Mary Immaculate Hospital/490041	2 Bernardine Dr	Newport News
220071	Massachusetts General Hospital	55 Fruit St	Boston
010011	Medical Center East	50 Medical Park East Dr	Birmingham
110107	Medical Center of Central Georgia	777 Hemlock St	Macon
040088	Medical Center of South Arkansas	700 W Grove	El Dorado
110036	Memorial Health University M.C.	4700 Waters Ave	Savannah

Provider ID	Hospital Name	Address	City
450404	Memorial Hermann Southwest	7/00 5	
450184	Hospital Memorial Hermann-Texas Medical	7600 Beechnut St	Houston
450068	Center Hermann-Texas Medical	6411 Fannin St	Houston
230004	Mercy General Health Partners	1500 Sherman Ave	Muskegon
050017	Mercy General Hospital	4001 J St	Sacramento
360056	Mercy Hospital Fairfield	3000 Mack Rd	Hamilton
160069	Mercy Medical Center of Dubuque	250 Mercy Dr	Dubuque
160153	Mercy Medical Center of Sioux City	801 5th St	Sioux City
160079	Mercy Medical Center/160079	701 10th St SE	Cedar Rapids
160083	Mercy Medical Center/160083	1111 6th Ave	Des Moines
380027	Mercy Medical Center/380027	2700 Stewart Pkwy	Roseburg
520048	Mercy Medical Center/520048	500 S Oakwood Rd	Oshkosh
450358	Methodist Hospital System	6565 Fannin St	Houston
100000	Methodist Medical Center of Oak		rioustori
440034	Ridge	990 Oak Ridge Tpke	Oak Ridge
440049	Methodist University Hospital	1265 Union Ave	Memphis
360076	Middletown Regional Hospital	105 McKnight Dr	Middletown
340002	Mission Hospitals-Memorial Campus	509 Biltmore Ave	Asheville
010007	Mizell Memorial Hospital	702 Main St	Орр
010113	Mobile Infirmary Medical Center	5 Mobile Infirmary Cir	Mobile
100034	Mount Sinai Medical Center	4300 Alton Rd	Miami Beach
330188	Mount St. Mary's H.C.	5300 Military Rd	Lewiston
360266	New Albany Surgical Hospital	7333 Smith's Mill Rd	New Albany
	New Hanover Regional Medical		
340141	Center	2131 S 17th St	Wilmington
340049	North Carolina Specialty Hospital	1110 W Main St	Durham
	North Florida Regional Medical		
100204	Center	6500 Newberry Rd	Gainesville
110198	North Fulton Regional Hospital	3000 Hospital Blvd	Roswell
250004	North Mississippi Medical Center- Tupel	830 S Gloster St	Tupelo
100122	North Okaloosa Medical Center	151 Redstone Ave SE	Crestview
330106	North Shore University Hospital		Manhasset
110029	Northeast Georgia Medical Center	300 Community Dr	
	Northeast Medical Center/340001	743 Spring St NE	Gainesville
340001		920 Church St North	Concord
340001	Northeast Medical Center/340001 Northern Nevada Medical Center	920 Church St North	Concord
290032 220035	Northshore Union Hospital	2375 E Prater Way 500 Lynnfield St	Sparks
110008	Northside Hospital-Cherokee	201 Hospital Rd	Lynn
			Cumming
110005	Northside Hospital & Modical Contor	1200 Northside Forsyth Dr	Cumming
500001	Northwest Hospital & Medical Center Northwest Medical Center-	1550 N 115th St	Seattle
040022	Springdale Vieutcal Center-	609 W Maple Ave	Springdale
070034	Norwalk Hospital	34 Maple St	Norwalk
370093	OU Medical Center	1200 N Everett Dr	Oklahoma City
190246	P&S Surgical Hospital	312 Grammont Street Suite 101	Monroe
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Provider ID	Hospital Name	Address	City
050115	Palomar Medical Center	555 E Valley Pkwy	Escondido
010054	Parkway Medical Center	1874 Beltline Rd SW	Decatur
440173	Parkwest Medical Center	9352 Park West Blvd	Knoxville
110007	Phoebe Putney Memorial Hospital	417 3rd Ave	Albany
100286	Physicians Regional Medical Center	6101 Pine Ridge Rd	Naples
390067	Pinnacle Health System	111 S Front St	Harrisburg
340040	Pitt County Memorial Hospital	2100 Stantonsburg Rd	Greenville
330331	Plainview Hospital	888 Old Country Rd	Plainview
340153	Presbyterian Orthopaedic Hospital	1901 Randolph Rd	Charlotte
340153	Presbyterian Orthopaedic Hospital	1901 Randolph Rd	Charlotte
510046	Princeton Community Hospital	122 12th St	Princeton
140155	Provena St. Mary's Hospital	500 W Court St	Kankakee
010090	Providence Hospital	6801 Airport Blvd	Mobile
230019	Providence Hospital/230019	16001 W Nine Mile Rd	Southfield
450002	Providence Memorial Hospital	2001 N Oregon St	El Paso
500024	Providence St. Peter Hospital	413 Lilly Rd NE	Olympia
120001	Queen's Medical Center	1301 Punchbowl St	Honolulu
110168	Redmond Regional Medical Center	501 Redmond Rd	Rome
180093	Regional Medical Center	900 Hospital Dr	Madisonville
340114	Rex Healthcare	4420 Lake Boone Trail	Raleigh
250081	Riley Hospital	1100 Constitution Ave	Meridian
140186	Riverside Medical Center	350 N Wall St	Kankakee
250069	Rush Foundation Hospital	1314 19th Ave	Meridian
140119	Rush University Medical Center	1650 W Harrison St	Chicago
340013	Rutherford Hospital Inc.	288 S Ridgecrest Ave	Rutherfordton
380033	Sacred Heart Medical Center/380033	1255 Hilyard St	Eugene
500054	Sacred Heart Medical Center/500054	101 W 8th Ave	Spokane
220082	Saints Medical Center	1 Hospital Dr	Lowell
360185	Salem Community Hospital	1995 E State St	Salem
100087	Sarasota Memorial Hospital	1700 S Tamiami Tr	Sarasota
110003	Satilla Regional Medical Center	410 Darling Ave	Waycross
420071	Self Regional Healthcare	1325 Spring St	Greenwood
490057	Sentara Virginia Beach General	1060 First Colonial Rd	Virginia Beach
490066	Sentara Williamsburg Reg.M.C.	100 Sentara Cir	Williamsburg
450056	Seton Medical Center/450056	1201 W 38th St	Austin
450668	Sierra Medical Center	1625 Medical Center Dr	El Paso
250040	Singing River Hospital	2809 Denny Ave	Pascagoula
430089	Siouxland Surgery	600 Sioux Point Rd	Dakota Dunes
260094	Skaggs Community Health Center	N Business Hwy 65	Branson
440135	Skyline Madison Campus	500 Hospital Dr	Madison
110165	Southern Regional Health System	11 Upper Riverdale Rd SW	Riverdale
100220	Southwest Florida Reg.M.C.	2727 Winkler Ave	Fort Myers
370097	Southwestern Medical Center	5602 SW Lee Blvd	Lawton
420007	Spartanburg Regional Medical Center	101 E Wood St	Spartanburg
230038	Spectrum Health-Butterworth Campus	100 Michigan St NE	Grand Rapids

Provider ID	Hospital Name	Address	City
220020	St. Anne's Hospital	795 Middle St	Fall River
040020	St. Bernard's Medical Center	225 E Jackson Ave	Jonesboro
240036	St. Cloud Hospital	1406 6th Ave North	Saint Cloud
070002	St. Francis Care	114 Woodland St	Hartford
330067	St. Francis Hospital/330067	241 North Rd	Poughkeepsie
440183	St. Francis Hospital/440183	5959 Park Ave	Memphis
	St. Francis Hospitals & Health		•
150033	Centers	1600 Albany St	Beech Grove
260183	St. Francis Medical Center/260183	211 St. Francis Dr	Cape Girardeau
230195	St. John Macomb Hospital	11800 E Twelve Mile Rd	Warren
150088	St. John's Health System	2015 Jackson St	Anderson
260065	St. John's Hospital/260065	1235 E Cherokee	Springfield
260020	St. John's Mercy Medical Center	615 S New Ballas Rd	Creve Coeur
050616	St. John's Pleasant Valley Hospital	2309 Antonio Ave	Camarillo
110039	St. Joseph Hospital/110039	2260 Wrightsboro Rd	Augusta
150047	St. Joseph Hospital/150047	700 Broadway	Fort Wayne
230029	St. Joseph Mercy Oakland	44405 Woodward Ave	Pontiac
110082	St. Joseph's Hospital of Atlanta	5665 Peachtree Dunwoody Rd NE	Atlanta
240063	St. Joseph's Hospital/240063	69 W Exchange St	Saint Paul
100260	St. Lucie Medical Center	1800 SE Tiffany Ave	Port Saint Lucie
260138	St. Luke's Hospital of Kansas City	4401 Wornall Rd	Kansas City
100151	St. Luke's Hospital/100151	4201 Belfort Rd	Jacksonville
510067	St. Luke's Hospital/510067	1333 Southview Dr	Bluefield
520083	St. Marys Hospital Medical Center	707 S Mills St	Madison
520019	St. Mary's Hospital/520019	2251 North Shore Dr	Rhinelander
	St. Mary's Medical Center of		
230077	Saginaw	800 S Washington Ave	Saginaw
240002	St. Mary's Medical Center/240002	407 E 3rd St	Duluth
040007	St. Vincent Health System	2 St. Vincent Cir	Little Rock
150010	St. Vincent Health-St. Joseph Hospital	1907 W Sycamore St	Kokomo
	St. Vincent's Hospital	810 St. Vincent's Dr	
010056	Strong Memorial I-University of	610 St. Vincent's Di	Birmingham
330285	Roches	601 Elmwood Ave	Rochester
440150	Summit Medical Center/440150	5655 Frist Blvd	Hermitage
	Sumner Regional Medical		<u> </u>
440003	Center/440003	555 Hartsville Pike	Gallatin
290003	Sunrise Hospital & Medical Center	3186 S Maryland Pkwy	Las Vegas
500129	Tacoma General Hospital	315 Martin Luther King, Jr. Way	Tacoma
100128	Tampa General Hospital	2 Columbia Dr	Tampa
110011	Tanner Medical Center	705 Dixie St	Carrollton
190008	Terrebonne General Medical Center	8166 Main St	Houma
450864	Texas Spine & Joint Hospital	1814 Roseland Blvd Ste 100	Tyler
010104	Trinity Medical Center/010104	800 Montclair Rd	Birmingham
030006	Tucson Medical Center	5301 E Grant Rd	Tucson
330394	UHS Is-Binghamton General	10-42 Mitchell Ave	Johnson City
450010	United Regional Healthcare System	1600 11th St	Wichita Falls
330226	Unity Hospital/330226	1555 Long Pond Rd	Rochester

Provider ID	Hospital Name	Address	City
	Via Christi Reg. Medical Center-St.		
170122	Fra	929 N St. Francis	Wichita
010089	Walker Baptist Medical Center	3400 Hwy 78 East	Jasper
310060	Warren Hospital	185 Roseberry St	Phillipsburg
050194	Watsonville Community Hospital	75 Nielson St	Watsonville
340010	Wayne Memorial Hospital/340010	2700 Wayne Memorial Dr	Goldsboro
	Wellmont Holston Valley Medical		
440017	Center	130 W Ravine	Kingsport
500148	Wenatchee Valley Hospital	820 N Chelan Avenue	Wenatchee
170175	Western Plains Medical Complex	3001 Ave A	Dodge City
330304	White Plains Hospital Center	Davis Ave at E Post Rd	White Plains
390045	Williamsport Hospital & Medical Center	777 Rural Ave	Williamsport
490005	Winchester Medical Center	1840 Amherst St	Winchester
100052	Winter Haven Hospital	200 Ave F NE	Winter Haven
010143	Woodland Medical Center	1910 Cherokee Ave SW	Cullman
	Yavapai Regional Medical Center-		
030012	West	1003 Willow Creek Rd	Prescott
390046	York Hospital/390046	1001 S George St	York